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EDITORIAL

Editorial

The New Medical Technologies and the Organizations of Medical Science and Treatment

Despite remarkable scientific and technological achievements during the 20th century, the 21st century has already witnessed additional new and profound changes in all areas of medical science and research, including innovations and discoveries in biology, cellular biology, genomics and proteomics, pharmaceuticals, medical devices, and information technology. Some have noted that this recent scientific avalanche has already brought about a complete "paradigm shift" in certain approaches to patient treatment, such as for cancer, Alzheimer's disease, organ and limb replacement, and various auto-immune system disorders (Niederhuber 2007).

Academic journals are hard-pressed to keep their audiences up-to-date on the unprecedented rapidity and scope of such changes. In the field of health services research, several journals have devoted entire issues and special sections to broad discussions of the products of the new science and their implications for patient treatment. See for example the broad policy discussions and analyses of trends in both *health services research* (*HSR)* and *Health Affairs* regarding health information technology ("Panel Discussion: Health Information Technology and Return on Investment." *Health Services Research* (Online Early Articles) doi: 10.1111/j.1475-6773.2007.00791.x), biotech drugs (September/October 2006 issue of Health Affairs), and transformative technologies and medical devices (Interview by John K. Iglehart "Transformative Technology: A Conversation with E. James Potchen and Bill Clarke." *Health Affairs* 26, (2), 2007: w227–35).

But the new discoveries keep coming, and it is becoming clear that even the biotech industries (which have long proclaimed their leadership in being "on the cusp" of translational science in genetics and proteomics) are feeling some level of uncertainty about their mastery of current knowledge and future applications. As an example, the assumed independence of genetic operation (the so-called "Central Dogma" of molecular biology, which assumes that each gene carries information needed to construct one specific protein)

provided the foundation for the biotech industry since the mid-1970s. However, recent reports note that these foundational assumptions of gene functioning are under dispute (Caruso 2007). The possibility of networked gene functions reverberates well beyond scientific and technical implications; because it throws patent rights and intellectual property claims into a stew of uncertainty, it is also outpacing the ability of our current legal and organizational structures to deal with its implications for changing care.

Within this context, this brief essay aims to focus attention on the related but often overlooked aspects of organizational change that are being (or will be) influenced by the new transformative technologies in medical care. At present, there appears to be a large and growing gap between the capacity of new medical sciences to develop innovative treatments and the capacity of scientific and treatment organizations to fully advance these innovations and adopt them for actual patient treatment. As that gap grows larger, we will more than likely see increases in systemic uncertainty in knowing how to proceed, increases in disparities in access to these new technologies, and increases in patient safety issues and quality of care concerns. That gap and its follow-on concerns will influence how we frame the discussion of medical innovation for the foreseeable future and might slow the pace of medical innovation in the long run.

The Organizations of Science and the Organizations of Care Delivery

Profound change in medical science has implications for change in at least two organizational sets: the organizations where that scientific development "happens" and the organizations where resultant transformation of medical treatment occurs. The first requires that we consider the linkage between research innovation and the wide variety of actors and organizations involved in translating new scientific discoveries into new products to be marketed for treatment use. This is the "bench to bedside" development chain, linking scientists, their labs, and/or universities to product development, testing, and marketing. Part of this puzzle involves questions about translational research and about entrepreneurship and product innovation among the producers of new medical treatments. The second organizational set that is profoundly influenced by new medical innovation occurs within the health care organizations where treatment is provided. This organizational set includes treating physicians,

their offices, groups, foundations, hospitals, diversified health systems, pharmacies, and delivery networks.

Both sets are experiencing change in internal organizational arrangements and in external linkages (or interorganizational structures and relationships, especially complex ownership arrangements, mergers and acquisitions, contract partnerships, etc.). Both organizational settings are influenced in a substantial way by three significant characteristics of their environments, i.e., market structures, fiscal intermediaries, and government policies and regulation. These three characteristics in turn form cross-cutting dimensions, influencing both the context for how new technologies impact organizational structures and serving themselves as catalysts for change, i.e., by influencing the relationship between technological change and organizational structure.

The remainder of this essay will provide several examples of studies that have tackled one or more of these complex interrelationships, featuring in particular, a new program developed by the National Cancer Institute that seeks to influence both where new science evolves and how new treatments are developed and deployed.

Change in the Organizations of Science: The Producers of New Technologies

Health services researchers have long studied the purchasers and provider organizations in health care, and traditional graduate curricula in health administration focus on these two sides of the industry. But both the research literature and the health administration curricula are remiss in evaluating and modeling the "producer" side of the industry, particularly in studying the implications of change in technologies, fostering effective innovation, and creating new business models and alliance formations among producers for the purchaser and provider sectors. Lawton R. Burns' (2005) work attempts to fill that void and thus improve our level of awareness and understanding of the new technological imperative in health care, the difficulties encountered by purchasers and providers in their attempts to control the diffusion of new technologies, and the impact of each sector on local and national economies. Burns provides a set of questions to use as the roadmap to organize what is known about several technological sectors, e.g., pharmaceuticals, biotechnology, genomics/proteomics, medical devices and information technology. This roadmap examines product characteristics and scientific framing, business models and strategies commonly used by firms in each sector, key success

factors, growth patterns, impact on the organization and delivery of health care, and competitive and regulatory forces that have shaped each sector. Burns also compared various theoretical frameworks (such as industrial organization, the resource-based view of the firm, value chain analysis, and organizational innovation and change) in terms of their ability to explain the adoption of merger and acquisition (M&A) strategies, the impact of M&A adoption on firm performance, value creation, and expected future innovation.

A key question posed by Burns, Nicholson, and Evans (2005) concerns the impact of M&A activity on the financial performance of pharmaceutical firms and on future innovation. They explore historical trends in big pharma and biotechnology firms from the mid-1980s through 2001, and examine how M&A activity has developed in distinct "waves" and for a variety of reasons. Their review concludes that M&A activity has had little impact on firm productivity or on new innovation. Despite the fact that classic industrial organization arguments for M&A stress the need to achieve economics of scale or scope and to speed entry into new markets, data show that the most recent wave of M&A events in this sector has instead concentrated on mega-mergers among the largest pharma firms. This has led to a highly concentrated pharma market, but few positive effects on innovation. These mega-mergers seem to be closely related to increased environmental pressures (such as competition from generics, dependence upon blockbuster drugs, the proliferation of HMOs and pharmacy benefit managers, and regulatory constraints). Further, the pharmaceutical industry's problem of "sagging pipelines" in Research and Development (R & D) has contributed to an upswing in the development of strategic alliance strategies between pharma firms and biotechnology firms. Strategic alliances tend to be somewhat more loosely defined agreements for cooperation between firms on specific projects or issues, often for a limited period of time, and do not involve complete changes in ownership or hostile acquisition. Some studies suggest that drugs developed within alliance structures tend to have a higher probability of success (completing phase II and III clinical trials) than drugs developed by single companies (Dimasi 2001; Nelson and Gueth 2001).

More recent conversations with leaders in the medical devices industry (Burns 2006, 2007) have provided interesting background information on the types of connective relationships typically observed in the devices industry. Unlike the pharmaceutical sector, M&A activity in the devices sector appears to be much lower, and interorganizational connections are far fewer, including contracts with group purchasing organizations and connections with venture

capital firms (Burns 2007). More commonly observed are "conversations" between specific hospitals and device manufacturers about long-term patient follow-up data collection, and linkages with individual clinicians concerning new product ideas.

Burns notes that "there is growing consensus that the task of drug discovery and development has become too complex for a single firm to handle on its own" (2005, p. 255). Whether this is also true of other new medical technologies remains to be seen, although some recent interviews and editorials point to such a possibility. There are similar needs for synergy across different firms as well as academia and state reimbursement systems in order to develop and launch transformative technologies in appliances, information systems, and genetics (Clancy 2006; Iglehart 2007). What we have not seen as yet are large-scale studies of interorganizational linkages between various actors regarding new technology development chains (e.g., scientific labs, universities, product development, testing and marketing firms) and the impact of such linkage strategies on innovation rates, start-up time, the rate of successful new product launches, or market coverage.

Change in Health Care Organizations Using the New Technologies

The organizations involved in treatment provision are also subject to substantial change as they ramp up to the challenges involved in providing safe and technologically appropriate environments for biologics, genetically modified organisms, and other targeted therapies. There are few detailed descriptions of the types of changes needed—though they exist at multiple levels and affect both organizational structures and processes—nor of the many strategic decisions that must be addressed by multiple stakeholders involved in each stage of decision-making. However, one particularly detailed example is provided by Bamford et al.'s (2005) description of the change approach used by a large teaching hospital within the NHS Trust located in London's Hammersmith Hospital, as it prepared to engage in clinical trials of new gene therapy agents. Bamford and coauthors reviewed all of the regulations covering gene therapy at multiple jurisdictional levels (national through local), and the risk assessment process used by the hospital to put into place an entire hospital environment, systems, and processes needed to allow gene therapy to proceed. This change process began with involving the core employees (clinical, technical, and managerial) at all levels who were committed to the goals of

gene therapy, requiring their understanding of why certain practices and procedures were needed, and their commitment to ongoing adherence to needed procedures. The core team was then able to win the support of different levels of regulatory bodies and the confidence of patients and staff throughout the hospital. In order to do this, the risk assessment team was tasked with developing key scenarios based on the three major pathways through which the gene agent travels: (1) the gene therapy pathway (how, where, and when the agent would be produced, brought to the hospital, stored, prepared, used, inactivated, and disposed of); (2) the patient pathway, covering all aspects of patient-agent interaction, patient location, confinement, monitoring, interaction with staff, visitors, follow-up, discharge and aftercare; and (3) the waste pathway, covering all aspects of waste generation, containment, transportation, destruction of genetically modified microorganisms in the waste, how waste would be disposed of, and how all steps recorded would be recorded. Through all three pathways the core team needed to consider all possible unexpected emergencies, all types of patient encounters with others both within and outside of the clinical environment, staff health concerns, and to set up accountability and reporting mechanisms at each level. This case provides an excellent model of the complicated set of redesign procedures generated by the adoption of gene therapy, and an "on the ground" example of a health care organization actively dealing with the provision of a new therapy on a system-wide level.

Health care organization redesign for the adoption of new transformative technologies (many of which are still in clinical trials) helps broaden access to those innovative treatments. However, access remains stymied without change in payment provisions by third-party payers and especially influential federal payers such as Medicare. For most of the last few decades, Medicare has typically denied coverage of new technologies still under investigation based on the supposition that coverage should be based on solid evidence of clinical effectiveness; this stance—and the funding precedence set by Medicare—in turn has governed funding decisions by most other third-party payers.

This approach has served as a reasonably effective and conservative basis for coverage of innovations in the past but, with the explosion of promising new therapies and access to direct-to-consumer information about them, demands by patients and physicians for access to new technologies (abetted by the producers of those technologies) have become particularly intense. To deal with these new demands, the Centers for Medicare and Medicaid Services (CMS) instituted an innovative approach to coverage known as "coverage with evidence development" (CED). (CMS drafted these guidelines

in 2005 and updated them in July 2006.) CED allows Medicare to cover specific new treatments or diagnostics but only for patients who agree to participate in either a clinical trial or registry.

The ideas behind CMS's policy have a lengthy history that is well described by Tunis and Pearson (2006) and others (e.g., Carino et al. 2006). Nonetheless, CMS's application of CED is generally considered a breakthrough policy that serves to ensure that Medicare's standard that care be "reasonable and necessary" would still be met while also providing the longitudinal data needed to analyze the cost effectiveness of new technologies. As Tunis and Pearson discuss, CED has the potential to ease the "log jam" in diffusing new technologies into actual use. However, there are major challenges to effective use of CED, including the following: (1) setting standards for when CED can be used for specific technologies; (2) establishing a process for prioritizing among promising new technologies; (3) dealing with ethical concerns about "coercive" pressures on patients to enroll in clinical trials and any subsequent inequalities in treatment that may arise from these requirements; and (4) developing appropriate models of informed consent (Tunis and Pearson 2006). Further, the adoption of CED-type policies by private insurers raises additional challenges about subsequent equity of access and cost effectiveness in the provision of care and diffusion of innovations.

Changing the Setting of the Science and the Delivery of New Technologies

A number of fairly large-scale demonstration projects supported by private foundations and the federal government have been recently launched or are soon to begin, which will provide models of organizational change to foster effective translation of new technologies to patient care (c.f., the Center for Medical Technology Policy; the Institute of Medicine's Roundtable on Evidence-based Medicine; the use of the national coverage determination process by CMS; and the Center for Comparative Effectiveness Information).

Of particular note here is the National Cancer Institute's (NCI) recently launched demonstration project: the NCI Community Cancer Centers Program (NCCCP); (see http://ncccp.cancer.gov). This project is unusual because it attempts to increase the number of early stage clinical trials available in smaller community hospitals in both urban and rural areas, and to upgrade the structure and process of cancer care delivery within community hospitals to support the new transformative technologies in cancer care. The NCCCP

aims to (1) bring more patients into a system of high-quality cancer care with access to state-of-the art treatment, (2) increase participation in clinical trials within the community setting, (3) reduce cancer health care disparities in both access and quality of care, and (4) improve information sharing among community cancer centers and between community cancer centers and the network of 63 NCI-designated Comprehensive Cancer Centers (principally based at large research universities).

Demonstration sites have been selected in 16 communities in 14 states (including both freestanding and system-connected community hospitals) to participate in a pilot program. A successful pilot will lead to the nationwide launch of the NCCCP in 2010. An important goal of this 3 year demonstration project is to study ways in which the community health care system can be electronically connected so that its patients can take part in the early phase trials of promising new biologics, an effort even more critical in this evolving period of highly personalized medicine. Significant attention is also focused on how to structurally upgrade community hospital infrastructure to allow for the collection, storage and sharing of blood and tissue samples needed for research. The pilot will assess how NCI's guidelines for collection and storage of specimens can be applied nationwide to benefit the entire cancer research community. The evaluation of this demonstration project will provide information on both clinical outcomes and organizational change, and will hopefully provide guidance on what types of changes in community cancer centers can be institutionalized to support ongoing access to new technologies in cancer care.

SUMMARY

This essay raises more questions than answers and leaves many important topics unaddressed such as intellectual property issues, comparative effectiveness research, disparities in access to innovative treatments, the diffusion of medical information technologies, and international comparisons. My primary purpose was to focus attention on a vitally important but understudied aspect of the new trends in medical technology: their impact and interdependence upon organizational changes. To that end, I have illustrated how medical innovation impacts both the organizations that develop the science and treatments and those where treatment occurs. These examples are intended to shed some light on the specifics of the resultant changes needed and especially on the complexity of the gaps that still need to be analyzed. Understanding the

size and depth of this gap is critical to any efforts to reap the benefits of this new age of medical research.

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Mary L. Fennell

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